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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,196	06/19/2001	Ben Hitt	CSIL-01P-006	9854

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EXAMINER

HIRL, JOSEPH P

ART UNIT	PAPER NUMBER
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2121

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,196

Applicant(s)

HITT, BEN

Examiner

Joseph P. Hirl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 081604.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to an AMENDMENT entered September 15, 2004 for the patent application 09/883,196 filed on June 19, 2001.
2. All prior office actions are fully incorporated into this office action by reference.

Status of Claims

3. Claims 1-23 are cancelled. Claims 24-48 are new. Claims 24-48 are pending.

Specification

4. The objection to the abstract and specification identified in the First Office Action of November 5, 2003 applies.

These objections must be corrected.

Claim Objection

5. Claim 27 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 26. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). To accomplish either claim, the conditions of the other are rendered by equivalence.

6. Claim 33 is objected to for being incomplete. Specifically line 3 and 4 state: "... determining whether the homogeneity, and providing." ... ?

7. Claim 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The term "random" can mean anything in both value and how it is determined and since there cannot be a truly random selection, at best, this claim is not limiting.

These objections must be corrected.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 28 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "high" is a relative term and renders the subject claims indefinite.

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10. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "best" is a relative term and renders the subject claims indefinite.

11. Claims 31, 33, 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "homogeneity" is a relative term and renders the subject claims indefinite.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 24, 31, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The abstract refers to "state of complex processes", the specification @ p 12, l 22 refers to "State of the Union addresses", the specification @ p 17, l 2 refers to "State of the Union addresses", and the specification @ p 17, l 15 refers to "Evaluation of Biological States". The specification is silent on a "first state" and a "second state".

14. Claims 28 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is silent on "... the biological sample known to be of the first state is derived via a high throughput bio-assay technique."

15. Claims 29, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is silent on "... a decision hyper-radius."

16. Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is silent on "best lead cluster map".

Claim Rejections - 35 USC § 101

17. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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18. Claims 24-48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The language of the claim raises a question as to whether the claim is directed merely to an abstract idea that is not tied to a technological art, environment or machine which would result in a practical application producing a concrete, useful, and tangible result to form the basis of statutory subject matter under 35 U.S.C. 101.12. Further, the claims can be implemented using pencil and paper and therefore is not embodied in a technological art.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

20. Claims 24-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Hu et al (WO 01/20043 referred to as Hu).

Claim 24

Hu anticipates determining the location of a first set of vectors and a second set of vectors in a vector space, each vector of the first set of vectors being; obtained from a data stream derived from a biological sample known to be of the first state, the second set of vectors including a plurality of vectors, each of

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the plurality of vectors of the second set of vectors being associated with a data stream derived from a biological sample known to be of the second state (**Hu**, p 4, l 24-33; Examiner's Note (EN): vectors are gene expression profiles; data is generated from the biological sample in response to a plurality of drugs via nucleic acid probe arrays; the location in vector space is determined by each of the profiles representing the response of the biological sample to one of the plurality of drugs); and identifying a cluster disposed within the vector space, the cluster containing at least one of the vectors of the first set of vectors, the cluster being associated with the first state for purposes of classifying a biological sample (**Hu**, p 4, l 24-33; EN: Para 24 applies; cluster analysis is performed).

Claim 25

Hu anticipates identifying a second cluster disposed within the vector space, the second cluster containing at least one of the vectors of the second set of vectors that is associated with a data stream derived from a biological sample known to be of the second state (**Hu**, p 4, l 24-33; EN: cluster analysis is performed).

Claim 26

Hu anticipates the first cluster and the second cluster do not overlap within the vector space (**Hu**, Fig. 8; EN: separated by a diagonal line).

Claim 27

Hu anticipates the first cluster is devoid of vectors of the second set of vectors, the second cluster is devoid of vectors of the first set of vectors (**Hu**, Fig. 8; EN: separated by a diagonal line).

Claims 28, 37

Hu anticipates the data stream derived from the biological sample known to be of the first state is derived via a high throughput bio-assay technique (Hu, p 4. I 24-33; EN: as by nucleic acid arrays).

Claims 29, 38

Hu anticipates the cluster includes a centroid and a decision hyper-radius (Hu, p 37. I 28-31; p 38, I 22-26; EN: log avg ratio is a centroid and a hyper-radius is a user modified threshold).

Claim 30

Hu anticipates abstracting the data stream derived from the biological sample known to be of the first state to obtain a vector that is associated with the data stream (Hu, p 4. I 28-29).

Claim 31

Hu anticipates processing a plurality of data strings against a predefined set of variables, thereby creating one or more processed strings, each data string being derived from a biological sample known to be of the first state or the second state (Hu, p 4. I 24-33); creating a best lead cluster map for the processed strings, wherein the best lead cluster map includes one or more clusters (Hu, p 4. I 24-33); determining a cluster homogeneity for the best lead cluster map (Hu, p 5. I 2-9); determining whether the homogeneity of the best lead cluster map is within an acceptable tolerance (Hu, p 4. I 12-15); and if it is determined that the homogeneity of the best lead cluster map is within the

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acceptable tolerance, providing the best lead cluster map (**Hu**, p 4. l 32-33; EN: Para 24 applies).

Claim 32

Hu anticipates if it is determined that the homogeneity of the best lead cluster map is not within the acceptable tolerance, defining a second set of variables different than the first set of variables (**Hu**, p 4. l 17-19).

Claim 33

Hu anticipates processing the plurality of data strings against the second set of variables; and repeating the creating, determining a cluster, determining whether the homogeneity, and providing (**Hu**, p 4. l 12-15).

Claims 34, 41

Hu anticipates the second set of variables are determined using a genetic algorithm (**Hu**, p 4. l 19-21; EN: genetic algorithm is a combination approach to the selection of variables, or a combination of the variable methods).

Claim 35

Hu anticipates the acceptable tolerance is input by a user (**Hu**, p 13. l 16-17; EN: such is k).

Claim 36

Hu anticipates wherein the predefined set of chromosome variables are input by a user (**Hu**, p 11. l 10-11).

Claim 39

Hu anticipates providing a plurality of data streams, each data stream being derived from a biological sample known to be of the first state or the

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second state (**Hu**, p 4. I 24-33); selecting a logical chromosome that specifies the location of data in each of the plurality of data streams (**Hu**, p 4. I 32-33; EN: the logical chromosome is a gene variable that is place in a cluster by statistical analysis); calculating a biological sample vector for each member of the set of data steams using the logical chromosome (**Hu**, p 4. I 24-33; EN: such is the statistical analysis process); finding the locations in a vector space of at least two non-overlapping data clusters that best fit the sample vectors (**Hu**, p 14. I 11-21); determining a cluster homogeneity for at least one of the at least two nonoverlapping data clusters (**Hu**, p 4. I 12-15; EN: degree of variation is synonymous with homogeneity); determining whether the homogeneity of the at least one of the at least two nonoverlapping data clusters is within an acceptable tolerance (**Hu**, p 4. I 12-15); and if it is determined that the homogeneity of at least one of the at least two nonoverlapping data clusters is within the acceptable tolerance, providing the locations in the vector space of the at least two non-overlapping data clusters (**Hu**, p 4. I 32-33; EN: Para 24, applies; such is done by cluster analysis using statistical analysis).

Claim 40

Hu anticipates if it is determined that the homogeneity of the at least two non-overlapping data clusters is not within the acceptable tolerance, defining a second logical chromosome different than the first logical chromosome (**Hu**, p 14. 11-21; EN: such is the construction of an ordered set of orthogonal variables).

Claim 42

Hu anticipates calculating a biological sample vector for each member of the set of data streams using the second logical chromosome; and repeating the finding step (Hu, p 4, 24-33; EN: the repeating step is the dimension reduction step).

Claim 43

Hu anticipates the number of preclassified biological samples is Greater than 20 (Hu, p 4, 24-33).

Claim 44

Hu anticipates the number of preclassified biological samples is between 20 and 200 (Hu, p 4, 24-33).

Claim 45

Hu anticipates the vector space has greater than 3 dimensions (Hu, p 4, 24-33).

Claim 46

Hu anticipates the vector space has between 5 and 25 dimensions (Hu, p 7, 18-24; EN: Hu easily accomplishes such dimensionality with a gene expression profile with a dimension that easily exceeds that of the applicant.).

Claim 47

Hu anticipates the logical chromosome is randomly selected (Hu, p 4, 24-33; EN: since random cannot be achieved, any gene will do).

Claim 48

Hu anticipates the location of each data cluster is the centroid

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of the sampled vectors that rest in the data cluster (Hu, p 37, l 28-31; p 38, l 22-26; EN: log avg ratio is a centroid).

Response to Arguments

21. No arguments based on prior office actions were submitted

Examination Considerations

22. The claims and only the claims form the metes and bounds of the invention. "Office personnel are to give the claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d, 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969)" (MPEP p 2100-8, c 2, l 45-48; p 2100-9, c 1, l 1-4). The Examiner has full latitude to interpret each claim in the broadest reasonable sense. Examiner will reference prior art using terminology familiar to one of ordinary skill in the art. Such an approach is broad in concept and can be either explicit or implicit in meaning.

23. Examiner's Notes are provided to assist the applicant to better understand the nature of the prior art, application of such prior art and, as appropriate, to further indicate other prior art that maybe applied in other office actions. Such

comments are entirely consistent with the intent and spirit of compact prosecution. However, and unless otherwise stated, the Examiner's Notes are not prior art but a link to prior art that one of ordinary skill in the art would find inherently appropriate.

24. Examiner's Opinion: Paras 22. and 23. apply. The Examiner has full latitude to interpret each claim in the broadest reasonable sense.

Conclusion

25. Claims 24-48 are rejected.

Correspondence Information

26. Any inquiry concerning this information or related to the subject disclosure should be directed to the Examiner, Joseph P. Hirl, whose telephone number is (571) 272-3685. The Examiner can be reached on Monday – Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anthony Knight can be reached at (571) 272-3687.

Any response to this office action should be mailed to:

Commissioner of Patents and Trademarks,

Washington, D. C. 20231;

or faxed to:

(703) 872-9306 (for formal communications intended for entry);

or faxed to:

(571) 273-3685 (for informal or draft communications with notation of

"Proposed" or "Draft" for the desk of the Examiner).

A handwritten signature in black ink, appearing to read 'Joseph P. Hirl'. The signature is stylized with a large, looped 'J' and a distinct 'H'.

Joseph P. Hirl

November 16, 2004